UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	
THIS DOCUMENT RELATES TO: *The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.*, Case No. 18-op-45090 *The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al.*, Case No. 17-op-45004	MDL No. 2804 Case No. 1:17-md-2804 Judge Dan Aaron Polster

DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR *DAUBERT* MOTION TO EXCLUDE THE OPINIONS OFFERED BY JAMES RAFALSKI

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I. INTRODUCTION

Plaintiffs retained James Rafalski, a former DEA investigator, to opine that certain defendants failed to "provide effective controls and procedures to guard against theft and diversion of controlled substances." He offers his personal views of: (1) Defendants' legal obligations, (2) Defendants' failure to meet those obligations, and (3) the resulting harm.

Rafalski's opinions should be excluded for three independent reasons.

First, Rafalski refused to disclose the bases for his so-called legal opinions. He testified that he relied on "legal guidance from DEA," but he refused to answer questions about that "guidance" at his deposition, hiding behind the Department of Justice's *Touhy* limitations on his testimony. Defendants have no way to challenge the bases for these opinions. When an expert fails to provide the disclosures required by Rule 26, "the sanction of exclusion is automatic and mandatory." *Ross v. Am. Red Cross*, 2012 WL 2090513, at *2 (S.D. Ohio Jan. 26, 2012).

Second, the "method" Rafalski used to identify "suspicious orders" has never been used in the real world—by DEA or anyone else. With reason. Rafalski assumes ***every*** order after a customer's initial flagged order is suspicious—and must be halted—while the initial order is investigated. Without assessing whether diligence was performed on ***any*** specific flagged order, he concludes that ***more than 90% of opioids shipped*** by certain distributors (not manufacturers) were "suspicious." Rafalski's testimony directly contradicts other Plaintiffs' experts who opine that most opioids were dispensed by compassionate doctors for legitimate medical purposes.

Most incredibly, Rafalski concludes that ***all*** "suspicious orders" were diverted for illicit use, and thereby caused the opioid epidemic. But Rafalski failed to investigate ***any*** pharmacy, much less look to determine if it operated as a "pill mill." His diversion opinions are based on nothing more than his own "belief." These opinions do not come close to satisfying *Daubert*.

II. BACKGROUND

A. Testimony on Defendants' Statutory and Regulatory Obligations

Rafalski worked as a DEA Diversion Investigator for 13 years. Since he left DEA in 2017, he has worked for plaintiffs in opioids cases. He claims now that DEA registrants who manufacture and distribute controlled substances are obligated to do much more than what is set forth under the law. *See* Ex. 1, Rafalski Rpt. at 1-46, 145-51. In fact, Rafalski admitted that many of the purported legal "requirements" he claims exist are not in the CSA or DEA regulations.

1. Rafalski's "key components" for suspicious order monitoring

For example, Rafalski dedicates nearly four pages of his report to what he terms "key components" that he would expect to see in a "suspicious order" monitoring and due diligence program, including, *e.g.*: grouping customers by "customer types," restricting customers' orders based on their "scope of practice," segregating customers by size based on order history, monitoring orders by "drug types," identifying thresholds based on customers' requirements "for the legitimate operation of their business," analyzing the "geographic distribution" of controlled substances with "relevant population information of end users," and conducting a variety of specific due diligence procedures. *Id.* at 37-40; Ex. 2, Rafalski Tr. 447:3-448:24, 449:6-20, 732:15-733:8.

None of these components appear in the CSA or DEA regulations. DEA's suspicious order monitoring regulation states only that registrants must design and operate a system to identify and report "suspicious orders," defined as orders of unusual size, frequency, or pattern. 21 C.F.R. § 1301.74(b). Nowhere does Rafalski disclose that he (or anyone else) ever articulated these "key components" as requirements while he was employed by DEA. *See* Ex. 2, Rafalski Tr. 453:12-18, 454:19-455:18. Rafalski conceded that these "key components" are not

"regulatory requirements" inasmuch as they are not "in a regulation, these specific things." *Id.* 441:10-442:4. But he claimed ***all*** of them are required under 21 CFR § 1301.74(b). *See id.*

2. Rafalski's requirements for manufacturers

Rafalski further claims—again without support—that manufacturer registrants are required to use chargeback and prescribing data to analyze downstream registrants that purchase manufacturers' products from distributors. Ex. 1, Rafalski Rpt. at 147. Rafalski acknowledged that this opinion was not based on the CSA, DEA regulations, or even official DEA guidance, but rather on his personal belief. Ex. 2, Rafalski Tr. 654:13-22; *see id.* 695:6-21. When asked whether he had ever seen a manufacturer's anti-diversion program that met his personal requirements, Rafalski claimed that he had seen only one such program, but promptly cited the DOJ's *Touhy* restrictions to ensure Defendants could not question him about it. *Id.* 662:3-663:16.

3. Rafalski's record-retention requirements

Rafalski opines that distributors must retain suspicious order reports and due diligence records "permanently"—***literally "forever"***—but he admitted that "suspicious order reports aren't part of the two-year [document] retention" regulation that appears in the Code of Federal Regulations. He also admitted the "CFR doesn't speak specifically to a due diligence record." *Id.* 124:10-126:25, 127:24-128:21. Other DEA witnesses testified that there is no requirement to document due diligence.[1] Yet Rafalski concluded that a lack of documented due diligence on a

[1] *See* Ex. 3, Wright Tr. 143:2-12 ("Q: And the exercise that the registrant goes through to do some due diligence to really bear out whether the order is, in fact, truly a suspicious order or not, that due diligence exercise, is there a regulatory requirement to document that due diligence? … A: No."); Ex. 4, Prevoznik 30(b)(6) Tr. 1212:13-19 ("Q: And I believe that you indicated that there was not any sort of requirement by the DEA of the maintenance of due diligence files, correct? … A: Yes."); *id.* 1220:20-1221:7 ("Q: Is there any sort of requirement, either by the DEA or by the registrant, to hold on to an actual suspicious order being reported to the DEA? … A: No.").

flagged order—even from 10 years ago or more—automatically means the registrant did not conduct due diligence and that the order is "suspicious." *Id.* 167:1-168:25.

4. Rafalski's reliance on undisclosed DEA information

Without statutory or regulatory support for these opinions, Rafalski said he relied on "legal guidance from DEA lawyers." But he refused to disclose that information:

> Q. During the course of the deposition, you've said on several occasions that your method for assessing the defendants' suspicious order monitoring systems is based in part on your experience, training and guidance from lawyers at DEA; is that correct? Do you remember that testimony?
> A. Yes, sir.
> Q. Okay. This is just a yes-or-no answer: Does the *Touhy* authorization that you received for today's testimony prevent you from disclosing the legal guidance from DEA lawyers that supports your opinions?
> A. So just so I understand the question. Does the *Touhy* letter prevent me from answering that question?
> Q. Right.
> A. I believe it does, yes.

Ex. 2, Rafalski Tr. 842:1-19. Rafalski admitted he offered a "legal conclusion." *Id.* 22:13-25.

B. Testimony on Rafalski's Assumption That All Orders Must Be Halted Following an Initial Flagged Order

According to Rafalski, at his direction, Plaintiffs' lawyers instructed another paid expert, Craig McCann, to analyze DEA's ARCOS data and Defendants' shipping data, using five made-for-litigation "flagging" methodologies. The flagging methods were purportedly meant to identify "suspicious orders" shipped by certain distributor—not manufacturer—Defendants.[2]

The crux of all of the flagging methods was Rafalski's assumption that distributors performed "either no or insufficient due diligence"—a premise grounded entirely on Rafalski's

[2] Rafalski testified that he did not identify ***any*** shipments by manufacturers that should have been reported as suspicious orders. *Id.* 633:13-634:2, 635:2-13. He also admitted that he did not apply his "key components" of a suspicious order monitoring system to manufacturers' systems, and does not know how they would apply. *See, e.g.*, *id*. 733:9-736:1 (no knowledge of how many customers Janssen sold to, how many orders per month Janssen received, Janssen's market share in the Track One jurisdictions, rates of diversion of Janssen's medications at issue, or even how many orders Janssen flagged and investigated).

claim that he did not see what he felt was sufficient documentation of due diligence, years—even decades—after that diligence would have occurred. *Id.* 183:7-14. He asserted, "as far as the DEA is concerned, if there's no documentation or record of it, a due diligence file, my opinion would be based on that that doesn't exist." *Id.* 171:1-12.

Based solely on this lack-of-diligence premise, Rafalski instructed McCann to use his flagging methods to identify a single, initial flagged order from each pharmacy to each distributor, and then to flag ***every subsequent order*** from that customer, regardless whether those subsequent orders would have been flagged independently. Without looking at ***any*** of those flagged orders, Rafalski concluded that ***all*** of those orders from that customer were "suspicious." *Id.* 468:25-469:6 (never reviewed any specific orders from McCann's report); *id.* 489:16-19 (never looked at any order McCann flagged); *see id.* 167:1-168:25 (if no due diligence is performed on an initial order, every subsequent order is deemed suspicious).

Rafalski testified, "when a suspicious order occurs … and there's no action taken, no due diligence action taken to dispel that suspicious order, that all the – ***all the orders from that point forward***, I'm considering them to be, you know, the result of suspicious orders." *Id.* 178:21-179:4 (emphasis added); *see id.* 166:12-18, 182:20-183:5. Rafalski opined that registrants must halt ***all*** of a customer's shipments until due diligence dispels suspicions on the one flagged order. *Id.* 133:12-134:2. He testified, "since the day I started at DEA, that's been the interpretation of the DEA." *Id.* 134:25-135:14; *see id.* 182:20-183:5. But he acknowledged the regulations do not say anything about whether and when to ship an order. "DEA doesn't inform a distributor if or when to ship an order or not to ship an order." *Id*. 134:25-136:6. "The responsibility for making the decision to ship rests with the supplier." Ex. 1, Rafalski Rpt. at 15; *id.* at 12 (legal authorities "leave unclear exactly when an order is deemed suspicious"); *see id.* at 10-13.

The nonsensical consequence of Rafalski's assumption is reflected in his conclusion that, for certain distributors, ***more than 90%*** of the oxycodone or hydrocodone shipped into Track 1 was in "suspicious orders." *See id.* at 41-46; *see also* Ex. 2, Rafalski Tr. 474:2-12. None of Plaintiffs' experts assessed how many orders would have flagged without use of this assumption, but Plaintiffs' data expert acknowledged that, using the flagging methods alone, "you don't flag very many orders." Ex. 5, McCann Tr. 294:24-295:7. Rafalski offered no opinion on how many legitimate prescriptions—to treat patients with cancer or post-surgical pain, for example—would have gone unfilled if more than 90% of the medications had not shipped. *Id.* 476:13-23.

Rafalski opines that the distributors addressed in his report "cause[d]" the opioid epidemic based on their failure to halt these shipments of "suspicious orders." Ex. 1, Rafalski Rpt. at 7. But Rafalski freely acknowledges he did not actually look at ***a single flagged order*** to determine whether it met his test and was ***actually*** suspicious. Ex. 2, Rafalski Tr. 489:16-19, 823:8-824:1. He testified that "there wasn't a requirement for me to actually find specific orders that were suspicious." *Id.* 192:16-18. Nor did he perform any analysis to see what due diligence was performed on any specific flagged order. *Id.* 489:3-15; *see id.* 366:17-367:2, 633:2-634:2.

C. Testimony on Diverted Opioids That "Caused" the Opioids Epidemic

Although Rafalski expressed no opinion in his report about the number of opioids that were diverted for illicit uses, he testified that every "flagged" order was not only "suspicious," but also that "***all of the controlled substances were diverted***." *Id.* 474:20-25 (emphasis added). But Rafalski failed to "look at any particular order to see whether it was diverted to an illicit channel." *Id.* 508:1-12. And he has no opinion on whether any flagged order led to any actual harm in the real world. *See id.*; *id.* 508:13-18. The only support Rafalski articulated for his diversion opinion was his own "belief." *Id.* 188:21-190:5. "Q. Okay. Other than your belief, is

it written down anywhere? Is there any research on that? Is there any data on that? Is this just -- just your belief? A. Not that I can cite." *Id.* 190:19-191:2.

III. ARGUMENT

A. Opinions With Undisclosed Bases Must Be Excluded

Rafalski testified that his "method for assessing the defendants' suspicious order monitoring systems" is based in part on "guidance from lawyers at DEA." *Id.* 842:1-19, 695:6-21. Rafalski refused to disclose that guidance. *See id*. These opinions must be excluded.

Under Rule 37(c), if a party fails to provide information required by Rule 26, "the party is not allowed to use that information" "unless the failure was substantially justified or is harmless." FED. R. CIV. P. 37(c). The rule requires "absolute compliance with Rule 26(a)." *Roberts ex rel. Johnson v. Galen of Virginia, Inc.*, 325 F.3d 776, 782 (6th Cir. 2003); *see also Vance v. United States*, No. 98-5488, 1999 WL 455435, at *3 (6th Cir. June 25, 1999) (footnote omitted) (Rule 37(c) "mandates that a trial court punish a party for discovery violations" unless the violation was harmless or substantially justified). The potentially sanctioned party bears the burden to prove harmlessness. *See Roberts*, 325 F.3d at 782 (citing cases).

In cases like this one, where an expert is prohibited from disclosing confidential or privileged information supporting his opinions, courts have excluded the expert's testimony under Rule 37. For example, in *Siemens v. Saint-Gobain Ceramics & Plastics, Inc.*, an expert based his opinions on studies he performed as a government contractor at the Los Alamos National Laboratory. 637 F.3d 1269, 1286 (Fed. Cir. 2011). Because his research involved national security matters, he was unable to disclose it in the litigation. *Id*. The district court excluded his opinions, reasoning that, "without any ability for Siemens to examine the studies that formed the basis of Dr. McClellan's opinions, 'there is clearly no principled way to test his

recollection and opinion.'" *Id*. (quoting 2008 WL 3862091, at *1 (D. Del. Aug. 20, 2008)). The Federal Circuit upheld the decision to strike the expert's opinions.

Here, Rafalski cited *Touhy* restrictions on his testimony and refused to disclose "legal guidance from DEA" that purportedly supports his opinions. Ex. 2, Rafalski Tr. 842:1-19. Nor has DEA produced this "guidance." Rafalski therefore lacks a disclosed basis for these opinions:

1. That the law required defendants to ***halt <u>all</u> shipments after identifying an initial suspicious order***, unless and until documented due diligence was performed to dispel suspicions on that order. He readily acknowledged that DEA does not tell DEA registrants when they can and cannot ship orders. *See id*. 134:25-136:6.

2. That ***his so-called "key components"*** of a suspicious order monitoring and due diligence system, set forth on pages 37 to 40 of his report, ***are regulatory requirements***. He admitted these components exceed the requirements set forth in DEA regulations. *See id.* 441:10-442:4, 447:3-449:20.

3. That the CSA and its implementing regulations ***require manufacturers to consider prescription and chargeback data***. He made clear that this testimony is based on his personal opinion, not anything in a statute or regulation. *See id.* 654:13-22, 695:6-21.

4. That ***suspicious order reports and due diligence records must be documented and retained "forever."*** He admitted no such requirement appears in DEA regulations. *See id.* 124:10-126:25.

These opinions have no basis in the CSA or DEA regulations.[3] If they have any foundation at all, it can only come from information Rafalski refused to disclose.

The prejudice to Defendants is clear and substantial. Any jury will be unfairly influenced by testimony from a former DEA investigator that Defendants broke the law by, for example, failing to retain documents, some more than ten years old. More fundamentally, Defendants cannot test Rafalski's opinions without disclosure of their bases. "A party should not be allowed to use confidential information as both a shield and a sword." *Siemens*, 2008 WL 3862091,

[3] Rafalski's opinions that Defendants violated federal law also constitute impermissible legal conclusions that apply his version of the facts to his version of the law. *See, e.g.*, *United States v. Gordon*, 493 Fed. App'x 617, 626-27 (6th Cir. 2012) (citation omitted) ("legal conclusions ... [are] properly excluded").

at *1. This is a basic tenet of Rule 26's disclosure obligations. It is also the reason Rule 37 requires mandatory exclusion for violations of those obligations. If Rafalski is not permitted to share the bases of his opinions, he should not be permitted to testify about those opinions at all.

B. Nothing Supports Rafalski's Conclusion That *All* Shipments Must Be Halted Following the Identification of *a Single* Suspicious Order

Federal Rule of Evidence 702 requires expert testimony to be "based on sufficient facts or data" and "the product of reliable principles and methods." FED. R. EVID. 702(b), (c). "Proposed testimony must be supported by appropriate validation—i.e., 'good grounds,' based on what is known." *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 590 (1993). Courts exclude expert testimony "where the methodology employed is either unreliable or entirely absent." *Botnick v. Zimmer, Inc.*, 484 F. Supp. 2d 715, 720 (N.D. Ohio 2007).

Here, Rafalski offers no basis for his opinion that any flagged order was actually "suspicious," much less that ***all*** orders must be halted following an initial suspicious order. His opinions regarding the number of opioids shipped in "suspicious orders" should be excluded.

First, to reach his conclusions about the orders he says are "suspicious," Rafalski testified that he created five flagging methods and provided them to Plaintiffs' counsel, and that he understood that counsel then provided those methods to McCann for his analysis. Ex. 2, Rafalski Tr. 500:18-501:15, 499:2-19. But Rafalski never discussed any of the results of McCann's flagging analyses with McCann. *Id.* 548:4-7. Rafalski conducted no tests of the five flagging methods to determine their ability to actually identify "suspicious orders." *Id.* 471:15-22. He said he believed McCann did some sort of testing but conceded, "I'm not sure on that." *Id.* 471:23-472:5. McCann did no such testing. He disclaimed expertise in suspicious order monitoring and offered no opinions on whether any of his flagged orders were

"suspicious." Ex. 5, McCann Tr. 108:2-109:4, 129:6-15, 269:1-270:9. McCann simply acted as the "calculator" that applied Rafalski's so-called methods to the data. *Id.* 129:6-15.

Instead of reviewing McCann's results—and far from confirming McCann applied the methodologies as Rafalski had instructed—Rafalski did not even look at McCann's report until after he put together the section of his own report concluding that all of the orders McCann "flagged" were "suspicious." Ex. 2, Rafalski Tr. 473:9-20; *see* Ex. 1, Rafalski Rpt. at 41-46 (identifying McCann's flagged order results as "suspicious orders that should not be shipped").

Rafalski's conclusion that all of McCann's flagged orders are "suspicious" therefore does not depend on any analysis of McCann's flagged orders—Rafalski performed no such analysis. It depends instead on Rafalski's separate conclusion that, in general, Defendants performed insufficient due diligence (a conclusion that in turn depends on his rewriting of the regulations to require permanent retention of diligence records). Rafalski did not look at a single order flagged by McCann to determine whether it was actually suspicious, or whether due diligence was actually performed on that flagged order that might have dispelled suspicions. *See* Ex. 2, Rafalski Tr. 489:3-19. He testified that "there wasn't a requirement for me to actually find specific orders that were suspicious." *Id.* 192:16-18. He may not have been asked to do that work, but his failure to do so renders his methods unreliable under *Daubert*.

With respect to manufacturers, Rafalski disclaimed any opinion that orders shipped by a manufacturer were suspicious, or that certain manufacturers failed to flag any specific order as suspicious. *See id.* 635:1-13 ("Q. And are you offering any opinion in this litigation that any particular order shipped by a manufacturer into Summit or Cuyahoga County was suspicious?... No, sir."); *id.* 823:8-824:8. Rafalski offered opinions that certain manufacturers' suspicious order monitoring systems were non-compliant, *see, e.g.*, Ex. 1, Rafalski Rpt. at 145-51, 159-62

(Janssen opinions), but he admitted he did not look to see whether those manufacturers complied with his so-called requirements. Ex. 2, Rafalski Tr. 732:15-735:13. These compliance opinions, too, should be excluded as lacking any sufficient basis.

Rafalski employed no method at all to determine whether McCann's flagged orders were "suspicious" under 21 C.F.R. § 1301.74(b). He simply regurgitated McCann's results. An expert's failure to test and validate his conclusions renders his testimony unreliable and therefore inadmissible. *See, e.g.*, *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000).

Second, even if Rafalski had tried to determine if the orders McCann flagged were suspicious (he admits he did not), there is no basis for Rafalski's conclusion that ***all*** shipments ***must be halted*** following the identification of a single ***initial*** suspicious order. To be clear, Rafalski opines that his flagging methods only identify a single order from a customer as "suspicious." After that first order is flagged, "every subsequent order would become a suspicious order." *See* Ex. 2, Rafalski Tr. 133:12-134:2, 167:1-168:9. McCann performed no computational analysis on any order beyond the initial flagged order; he simply flagged all other orders because they followed the first one. *See* Ex. 5, McCann Tr. 270:24-271:22.

Rafalski cites no support for his opinion that "when you don't do due diligence, that makes every subsequent order a suspicious order." Ex. 2, Rafalski Tr. 184:13-15. Neither the CSA nor the regulations describe the nature of any required due diligence, or when a distributor may ship an order. *Id*. 134:25-136:7; Ex. 1, Rafalski Rpt. at 12. And nothing in the law, DEA guidance, or basic common sense suggests that a system that identifies more than 90% of opioids as "suspicious" could effectively identify potential diversion. Such a system is not identifying anything unusual or "suspicious," as the regulation requires. By flagging almost everything, Rafalski's method fails to highlight much of anything for further scrutiny. Unsurprisingly,

Rafalski points to no real-world suspicious order monitoring system that operates like this. His method is made for litigation. It does not withstand scrutiny under *Daubert*.

Third, Rafalski's opinion that such a large proportion of distributors' opioid shipments were part of "suspicious orders" that were diverted is contradicted by the opinions of three other Plaintiffs' experts, Drs. Lembke, Schumacher, and Kessler. These experts opine that legitimate prescribing by well-intentioned doctors accounted for the vast majority of prescriptions—and therefore orders—of opioids.[4] Dr. Lembke denied that "pill mills" or "rogue" doctors account for the opioid epidemic, and pointed instead to prescribing according to the prevailing standard of care.[5] Rafalski's opinion is also contrary to DEA's statement that "nearly every prescription" for opioids issued by a U.S. physician was "legitimate."[6] If the vast majority of opioids were legitimately dispensed, then no diversion—at least not from the pharmacy—occurred.[7]

C. Nothing Supports Rafalski's "Causation" Conclusion That Any Medication Included in Any Flagged Order Was Diverted

Rafalski's testimony about the number of opioids that supposedly were "diverted" following shipment is particularly egregious. It lacks ***any*** basis, much less a sufficient basis under Rule 702. With a wave of the hand, Rafalski testified that every single pill contained in every single order that McCann flagged was also diverted for unlawful use. This diversion

[4] Ex. 6, Lembke Tr. 223:25-224:15 ("[P]ill mill doctors, doctors who … are committing crimes are not the major factor…. [T]he vast majority of opioids prescribed in this country are prescribed not by such ethically compromised doctors, but by well-intentioned doctors who have been prescribing according to the misrepresentation of the evidence made available to them by the actions of the defendants."); Ex. 7, Schumacher Rpt. ¶ 60 ("It is my opinion that as a result of direct-to-consumer and direct-to-physician marketing, as well as other efforts by opioid manufacturers to promote the widespread and long-term use of opioids, that the risk of addiction was trivialized, and the benefits of long-term opioid use overstated. Physicians were influenced by these efforts and a cautious and conservative approach to the use of opioids for the treatment of pain was replaced with much more liberal prescribing practices."); Ex. 8, Kessler Rpt. ¶ 74, Conclusions ¶ 47.

[5] Ex. 6, Lembke Tr. 223:25-224:15.

[6] Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716, 52,721 (DEA Sept. 6, 2015).

[7] Ex. 9, Griffin Tr. 43:25-44:22 (compliance and enforcement director for the Ohio State Board of Pharmacy testifying that "diversion is when a pharmaceutical prescription is in any way redirected from its legitimate medical use to an illicit use" and does not occur when a registered dispenser transfers prescription opioids to an outpatient who presents a legal prescription written by a licensed prescriber).

opinion does not appear in Rafalski's report. He offered it for the first time at deposition. But there is a world of difference between identifying an order as "suspicious" and concluding that it was diverted for illicit use. Rafalski completely fails to bridge that gap. His causation opinions about the number of diverted opioids do not withstand the lightest scrutiny under *Daubert*.

First, Rafalski agreed that McCann presents the results of his flagging analyses only in the aggregate. Ex. 2, Rafalski Tr. 514:8-515:9 (discussing McCann's flagging results, presented in McCann's Appendix 10). None of McCann's analyses show the number of flagged orders from any individual customer. Rafalski agreed, "you can't tell anything about any individual pharmacy" from McCann's aggregated charts, including anything about the pharmacy's customer base, location, or even how much oxycodone or hydrocodone shipped to that pharmacy. *Id.* 514:23-515:4, 515:25-516:24. Rafalski also agreed there are legitimate reasons a pharmacy's need for opioids might increase—reasons that have nothing to do with diversion, such as a hospital opening nearby. *Id.* 65:19-66:16. Rafalski has nothing to say about whether any pharmacy in Track 1 was operating as a "pill mill." He did not even try to figure that out. As other Plaintiffs' experts explain, "pill mills" were not the problem; the opioid epidemic was not caused by diversion but by too much (in hindsight) legitimate prescribing. *See supra* n.7.

Second, Rafalski testified that he also "didn't do any analysis to see whether any specific suspicious order caused the diversion of any specific pills." *Id.* 469:20-470:1. He did not look at McCann's flagged orders ***at all***, much less did he look to see what happened to those orders after they shipped. "I don't have any direct knowledge of what happened to any drugs that were distributed to each of the pharmacies. I didn't conduct any analysis as of today that would give me that knowledge." *Id.* 582:15-19. Rafalski therefore has nothing to say about the number of

opioids he thinks should have been shipped. "[T]o put a calculated number, I can't do that." In fact, he said it was an "impossible task." *Id.* 208:2-209:2.

Without looking at the circumstances of each pharmacy order, there is no way to determine whether diversion is occurring at that pharmacy. Rafalski admitted that "in most cases the amount of the drug alone wouldn't immediately make [an order] suspicious." *See id.* 693:19-21. And, as DEA's 30(b)(6) witness testified, suspicious orders "may or may not" lead to diversion. Ex. 4, Prevoznik DEA 30(b)(6) Tr. 307:18-308:17; *id.* 281:22-282:12; *see also* Ex. 3, Wright Tr. 212:24-213:2 (agreeing that "being reported as suspicious does not imply necessarily that [an order] will be diverted"). Volume of shipments alone is therefore far from sufficient to identify diversion. *See In re Masters Pharm., Inc.*, 80 Fed. Reg. 55,418, 55,426 n.15 (DEA Sept. 15, 2015) (DEA rejecting "the allegation that the volume of dosage units distributed to the pharmacies alone establishes that the Respondent 'knew or should have known' that the 'prescriptions were issued for other than a legitimate medical purpose and outside the usual course of professional practice'").

Third, Rafalski also offers no opinion whether any prescription was illegitimate, or whether (as three other Plaintiffs' experts testified) most doctors prescribe opioids appropriately. Ex. 2, Rafalski Tr. 201:11-202:16. He has "no opinion about whether any particular order that was flagged as suspicious led to someone's addiction, overdose or death." *Id.* 508:1-18.

Despite all of this, Rafalski said, "if it's identified as a suspicious order by unusual size or unusual frequency or deviation from—you know, substantial deviation from pattern, so to me that puts it as a probable, greater than 51% that it's going to be diverted because it's been identified." *Id.* 189:18-24. He offered no support for this speculation other than his "belief." *Id.* 190:19-191:2. Any "methodology" is "entirely absent." *Botnick*, 484 F. Supp. 2d at 720. There

is far too great an analytical gap between the data and the opinion proffered. *See Gen. Elec. v. Joiner*, 522 U.S. 136, 146 (1997). Rafalski's opinions on the number of opioids diverted after being shipped to DEA-registered pharmacies should be excluded.

IV. CONCLUSION

Rafalski's four opinions based on undisclosed legal guidance must be excluded under Rule 37(c). His opinions based on the assumption that all orders after a customer's initial flagged order are "suspicious," and must be halted pending due diligence on that first flagged order, are unreliable and should also be excluded. Finally, Rafalski's opinion that all "suspicious orders" were diverted—more than 90% of opioids shipped by certain Defendants—lacks any basis whatsoever, is totally speculative, and should be excluded under Rule 702 and *Daubert.*

Dated: June 28, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of June, 2019, a notice of the foregoing has been served via CM/ECF to all counsel of record, and copies have been served on the same by email.

/s/ Katherine M. Swift
Katherine M. Swift

Attorney for Walgreen Co. and Walgreen Eastern Co.